



Please type a plus sign (+) inside this box. FORM PTO/SB/08

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 3

**Complete if Known**

Application Number	10/633,475
Filing Date	07/31/2003
First Named Inventor	Derek O'Hagan
Group Art Unit	1642
Examiner Name	Unassigned
Attorney Docket Number	PP01388.211

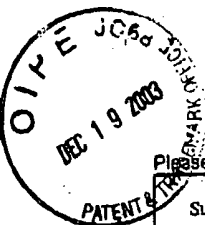
Examiner Initials*	Cite No. 1	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Class/Subclass		
32	1.	5,643,605	424/279.1	Cleland et al.	07/01/1997
32	2.	5,902,565	424/1.29	Cox et al.	05/11/1999
32	3.	4,413,057	424/244.1	Carlo et al.	11/01/1983
32	4.	5,010,183	435/262	Macfarlane	04/23/1991
32	5.	6,086,901	424/283.1	O'Hagan et al.	07/11/2000
32	6.	5,871,747	424/208.1	Gengoux-Sedlik et al.	02/16/1999
32	7.	5,869,103	424/501	Yeh et al.	02/09/1999
32	8.	5,783,567	514/44	Hedley et al.	07/21/1998
32	9.	5,830,430	424/1.21	Unger et al.	11/03/1998
32	10.	5,630,922	204/499	Eswarakrishnan et al.	05/20/1997
32	11.	4,534,996	427/498	Rembaum et al.	08/13/1985
32	12.	5,714,354	435/101	Arnold et al.	02/03/1998

Examiner Initials*	Cite No. 1	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T
		Office <sup>2</sup>	Number <sup>1</sup>	Class/Subclass			
32	1.	WO	96/20698	A61K 9/51	University of Michigan	07/11/1996	
32	2.	WO	95/24929		Brown University	09/1995	
32	3.	WO	98/33487	A61K 9/16	Chiron Corporation	08/06/1998	
32	4.	WO	98/10750	A61K 9/16		03/19/1998	
	5.	WO	96/20698	A61K 9/51		07/11/1996	
32	6.	WO	94/28879	A61K 9/16		12/22/1994	
32	7.	WO	94/15635	A61K 39/385		07/21/1994	
32	8.	WO	97/02810	A61K 9/16	University of Nottingham	01/30/1997	
32	9.	WO	97/24447	C12N 15/63	Chiron Viagene, Inc.	07/10/1997	

Examiner Signature		Date Considered	12/15/04
--------------------	--	-----------------	----------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation, if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English Language Translation is attached.



Docket No.: PP01388.211

Please type a plus sign (+) inside this box. FORM PTO/SB/08

Substitute for form 1449A/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/633,475		
		Filing Date	07/31/2003		
		First Named Inventor	Derek O'Hagan		
		Group Art Unit	1642		
		Examiner Name	Unassigned		
Sheet	2	of	3	Attorney Docket Number	PP01388.211

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
32	1.	Moore et al., <i>Vaccine</i> , Vol. 13, no. 18, 1995, pp. 1741-1749	
32	2.	Haynes et al., <i>AIDS Research and Human Retroviruses</i> , Vol. 10, Supplement 2, 1994, pp. S42-S45.	
32	3.	A.G.A. Coombes et al., "Single Dose, Polymeric, Microparticle-based Vaccines: The Influence of Formulation Conditions on the Magnitude and Duration of the Immune Response to a Protein Antigen," <i>Vaccine</i> , Vol. 14, no. 15, 1996, pp. 1429-1438.	
32	4.	Jacqueline D. Duncan et al., "Poly(lactide-co-glycolide) Microencapsulation of Vaccines for Mucosal Immunization," <i>Mucosal Vaccines</i> (Academic Press, 1996), pp. 159-173.	
32	5.	John H. Eldridge et al., "Biodegradable and Biocompatible Poly(DL-Lactide-Co-Glycolide) Microspheres as an Adjuvant for Staphylococcal Enterotoxin B Toxoid Which Enhances the Level of Toxin-Neutralizing Antibodies," <i>Infection and Immunity</i> , Vol. 59, no. 9, 1991, pp. 2978-2986.	
32	6.	John H. Eldridge et al., "New Advances in Vaccine Delivery Systems," <i>Seminars in Hematology</i> , Vol. 30, no. 4, 1993, pp. 16-25.	
32	7.	Deborah A. Higgins et al., "MF 59 Adjuvant Enhances the Immunogenicity of Influenza Vaccine in Both Young and Old Mice," <i>Vaccine</i> , Vol. 14, no. 6, 1996, pp. 478-484.	
32	8.	Ying Men et al., "Induction of a Cytotoxic T Lymphocyte Response by Immunization with a Malaria Specific CTL Peptide Entrapped in Biodegradable Polymer Microspheres," <i>Vaccine</i> , Vol. 15, no. 12-13, 1997, pp. 1405-1412.	
72	9.	Ryusuke Nakaoka et al., "Enhanced Antibody Production Through Sustained Antigen Release from Biodegradable Granules," <i>Journal of Controlled Release</i> , Vol. 37, 1995, pp. 215-224.	

Examiner Signature		Date Considered	12/15/04
-----------------------	--	--------------------	----------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation, if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English Language Translation is attached.



Substitute for form 1449A/PTO		<b>Complete if Known</b>			
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/633,475		
		Filing Date	07/31/2003		
		First Named Inventor	Derek O'Hagan		
		Group Art Unit	1642		
		Examiner Name	Unassigned		
Sheet	3	of	3	Attorney Docket Number	PP01388.211

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
32	10.	D.T. O'Hagan et al., "Long-Term Antibody Responses in Mice Following Subcutaneous Immunization with Ovalbumin Entrapped in Biodegradable Particles," <i>Vaccine</i> , Vol. 11, no. 9, 1993, pp. 965-969.	
32	11.	D.T. O'Hagan, "Biodegradable Microparticles for Oral Immunization," <i>Vaccine</i> , vol. 11, 1993, pp. 149-154.	
32	12.	Michael F. Powell et al., eds., <i>Vaccine Design: The Subunit and Adjuvant Approach</i> (New York: Plenum Press, 1995), p 183.	
32	13.	Hongkee Sah et al., "Continuous Release of Proteins from Biodegradable Microparticles and In Vivo Evaluation of Their Potential as a Vaccine Adjuvant," <i>Journal of Controlled Release</i> , Vol. 35, 1995, pp. 137-144.	
32	14.	H.M. Vordermeier et al., "Synthetic Delivery System for Tuberculosis Vaccines: Immunological Evaluation of the <i>M. tuberculosis</i> 38 kDa Protein Entrapped in Biodegradable PLG Microparticles," Vol. 13, no. 16, 1995, pp. 1576-1582.	
32	15.	Bertling et al., "Liposomes, Viral Capsids, and Nanoparticles as DNA Carriers," <i>Biotechnology and Applied Biochemistry</i> , Vol. 13, 1991, pp. 390-405.	
32	16.	Christine Chavany et al., "Adsorption of Oligonucleotides onto Polyisohexylcyanoacrylate Nanoparticles Protects Them Against Nucleases and Increases Their Cellular Uptake," <i>Pharmaceutical Research</i> , Vol. 11, no. 9 (1994), pp. 1370-1378.	
32	17.	Elias Fattal et al., "Biodegradable Polyalkylcyanoacrylate Nanoparticles for the Delivery of Oligonucleotides," <i>Journal of Controlled Release</i> , Vol. 53 (1998), pp. 137-143.	

Examiner Signature	<i>[Signature]</i>	Date Considered	12/15/04
--------------------	--------------------	-----------------	----------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 608. Draw line through citation, if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English Language Translation is attached.